REMARKS

Reconsideration of the application is respectfully requested, if view of the following remarks.

As requested by the Office, applicants enclose a new declaration.

WO 98/34630, as the Examiner has acknowledged, does not disclose antibodies, or fragments thereof, according to claim 1.

Aoubala et al disclose monoclonal antibodies prepared against Human Pancreatic Lipase – see abstract. However, it is unclear that there is any disclosure or suggestion given by this reference that the types of antibodies of the present invention would have any effect against human dietary lipase.

STN accession number 1998286804 EMBASE (English Language abstract) does disclose that the inhibition of pancreatic lipase offers the opportunity to intensify the weight reducing effect of a diet. However, it is not apparent that any details are given, or suggestions made, that the antibodies, of fragments thereof according to the present invention could be used.

WO 99/46300 discloses the use of VHHs in the preparation of products to provide stability of antibody specificity under conditions whereby normally lower eukaryotes or traditional antibodies are killed or inactivated (see page 7 fourth paragraph). However, it is unclear where there is any disclosure in WO 99/46300 of the ability of the disclosed anti-bodies to bind to human dietary lipases. Furthermore, it is questioned whether there is any teaching or suggestion that

such antibodies would be effective against such lipases or that they could be used to inhibit the same so as to aid in reducing the digestion of dietary fats.

US 6,558 936 discloses antibodies in therapeutic pharmaceutical applications to inhibit the activity of lipase protein (see abstract). However it is not apparent that there is any teaching concerning the possibility of using the antibodies of the invention to bind with human dietary lipases and so to provide the advantages provided by the present invention.

The Office has combined the teaching of WO 99/46300 (which discloses VHH antibodies but does not disclose their effectiveness against human dietary lipases) with the teaching of Aoubala et al (who teach monoclonal antibodies against human pancreatic lipases but not VHH antibodies). Even this combination would not result in the present invention and would not result in an expectation in one skilled in the art that the antibodies, or fragments thereof, would bind specifically to human dietary lipases. Indeed, it is submitted that this combination would produce the opposite expectation in one skilled in the art! It is unclear that there would be motivation for one skilled in the art to produce a VHH version of an inhibiting anti HPL- antibody based on the combination of the two aforementioned references because it is unclear that there would be any expectation of success. It then follows that once one skilled in the art would not be motivated to make such a modification so there is no need to consider further what may be done thereafter.

The Office has combined the teaching of at least three documents (and has really used up to 5) to try to argue that the present invention is obvious. It is submitted that this in itself helps suggest that there were many steps to consider for the inventors of the present invention and it was not a obvious step to address them

all and to arrive at the present invention. Even this level of combination of documents by the Examiner does not lead directly and unambiguously to the present invention.

Therefore, it is submitted that the above combination of teachings does not render the present invention obvious.

The Office has objected to claims 1-3, 9 and 10 under 35 U.S.C. 103(a) as being unpatentable over the 3 references given in point 14.

Comments are given above regarding the disclosures of each of the three references (US 6,558,936, WO 99/46300 and Aoubala et al) and these apply equally here. The same comments apply about the combination of the teaching of WO 99/46300 and Aoubala et al and once this combination would not render the present invention obvious to one skilled in the art, the further combination with US 6,558,936 adds nothing.

Therefore, it is submitted that the above combination of teachings does not render the present invention obvious.

With respect to the Section 112 rejection, the specification describes fully an antibody or a fragment thereof, which comprises a heavy chain variable domain derived from an immunoglobulin naturally devoid of light claims.

Human dietary lipases are of known structures and so one skilled in the art would recognize the antibodies, or fragments thereof, which will bind to these lipases. Additionally, one skilled in the art is given information on the structure of the

antibodies, or fragments thereof. It is therefore submitted that taking both characterisations 1 and 2 above into consideration, one skilled in the art would be able to visualize or recognize the identity of the members of the genus.

The specification describes how to prepare antibodies of the invention, or fragments thereof (see in particular Examples 1, 2 and 4). The efficiency of these antibodies, or fragments thereof, in inhibiting human lipase activity (which is the desired outcome of the invention) is shown in Examples 3 and 5. Details of food products are given on page 10 last paragraph to page 11 line 14 of the application as filed. It is submitted that the specification discloses how to make and use antibodies, or fragments thereof, which are capable of binding specifically to one or more human dietary lipases.

In view of the foregoing, it is respectfully requested that the application be allowed.

Respectfully submitted,

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